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6449	7590	01/03/2006	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C.			CLOW, LORI A	
1425 K STREET, N.W.				
SUITE 800			ART UNIT	
WASHINGTON, DC 20005			PAPER NUMBER	
			1631	

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/807,943

Applicant(s)

HONG ET AL.

Examiner

Lori A. Clow, Ph.D.

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-17 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' response, filed 19 September 2005, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-17 are currently pending.

#### **Information Disclosure Statement**

The information disclosure statement filed 28 June 2005 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

#### **Claim Rejections - 35 USC § 112-New Matter**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

Art Unit: 1631

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant has not provided support for the amendments to claims 1, 12, 17 and claims dependent therefrom. Further, no support for the newly cited limitations is found in the specification as originally filed. Specifically, the creation of a data record containing steps for associating a value with the labeled DNA marker, wherein the value **corresponds** to the classified peak intensity of the signal emitted from the labeled DNA marker and entering the value into the data record at a **predetermined location** within the data record, wherein the location of each said value within the data record is a function of the size.

Further, the “information” of claim 17 is not identified in the specification, nor is a “transformed” DNA marker. The claims are rejected for containing *new matter*.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described

Art Unit: 1631

in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues that the claims “no longer require that each DNA fragment have a peak intensity”. Claims 1 and 12 “no longer require determining a sequence of fragments according to values of said bins, therefore claims 1 and 12 no longer require the features that the Examiner had objected to”. While Applicant has amended the claims to overcome the outstanding enablement rejection, to which the Examiner rejected claims 1 and 12 for limiting the peak intensity of the DNA fragment to be solely from the DNA fragment and for lacking guidance such that the values of bins determines the sequence of fragments, the claims are still not enabled for the following reasons:

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must be able store DNA fingerprint data comprising the steps of providing the DNA fingerprint, which has associated with it peak intensities; determine the size of the labeled DNA markers; measure the peak intensity; classify the peak intensity; align the sizes of labeled DNA markers into one of a discrete size bins that have a value that correlates to a base pair number; and then create a data

Art Unit: 1631

record that contains values corresponding to classified peak intensity of the signal emitted from the labeled DNA marker. For the reasons discussed below, this constitutes undue experimentation.

b) and c) The specification provides no examples for creating a data record with such criteria. Further, the specification provides no connection between the values generated in steps (a)-(e) and the values of step (f). How do these generated values, each different, create a data record that is presumably for storing DNA fingerprint data. What constitutes the DNA fingerprint data? Is it the value of peak intensity of step (e) or is it the value of base pair number from steps (a)-(e)?

d) The invention is drawn to methods, a computer program product, and a computer system for storing DNA fingerprint data.

e) and g) It would have been well known in the art that fingerprint data can be stored in bins, such as taught by Ghosh et al. (Genome Methods (1997) Vol. 7, pages 165-178). Ghosh teaches a specific method for genotyping that involves sizing of alleles using three dyes of fluorescent labeling. Allele sizes for fragments are estimated using interpolation after fitting a calibration curve to the mobility data for size standards. There are specific parameters by which “binning” and “allele calling” are defined (page 166, columns 1 and 2). These include integer representations that are characteristic of a bin.

The instant claims, however, fail to provide a connection between the steps such that values are associated to a fingerprint. Without such nexus, the claims are not enabled.

f) The skill of those in the art of molecular biology is high.

Art Unit: 1631

h) The claims are broad because they are drawn to storing fingerprint data based upon generation of values which have no connection to one another such that a data record can be created. Further, there is no identification of a fingerprint parameter such that one of skill in the art would know how to generate a fingerprint for storage in the method. The skilled practitioner would first turn to the instant specification for guidance to practice such methods. However, the instant specification does not provide specific guidance to practice these embodiments. As such, the skilled practitioner would turn to the prior art for such guidance, however, the prior art shows that such fingerprint generation requires specific value parameters to lend meaning to the data. Finally, said practitioner would turn to trial and error experimentation. Such represents undue experimentation.

**Claim Rejections - 35 USC § 112-2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 12 recite steps (a) – (f) for storing DNA fingerprint data. However, it is unclear what constitutes the fingerprint data in these claims. Is it the values associated with base pair number? Is it the values associated with peak intensities? Clarification is requested.

Art Unit: 1631

**Claim Rejections - 35 USC § 102**

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 17 remains rejected under 35 U.S.C. 102(b) as being anticipated by GeneScan®

Reference Guide (1997), for the reasons set forth in the previous Office Action.

Applicant argues that the Guide does not disclose “a sequence of transformed DNA marker signal peak intensity symbols”. This is not persuasive. The Guide, at page 8-12, describes binning, in which markers are based upon fragment length of products estimated by gel or capillary electrophoresis. Further, alleles are binned in a histogram, thus contain symbols. No claims are allowed.

**Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



Art Unit: 1631

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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December 8, 2005

Lori A. Clow, Ph.D.

Art Unit 1631

*Lori A. Clow*

MARJORIE A. MORAN  
PRIMARY EXAMINER

*Marjorie A. Moran*  
12/18/05